

FOR THE DISTRICT OF COLUMBIA

* * * * *

in a letter to former Congressman Ronnie Shows (D-MS) dated November 8, 1999. This was in response to a letter my son sent Rep. Shows dated October 10, 1999.

2. In the Army letter to Rep. Shows, at page 2, paragraph 2, the Army acknowledged that my son was given anthrax vaccine. This was two years before the commencement of shots under the mandatory anthrax vaccine immunization program (AVIP), which commenced in March 1998. The Army letter makes it seem that my son simply received the two vaccines simultaneously. However, an industry trade publication featuring an interview with Dr. Sadoff indicates that the combination of Anthrax vaccine and Hepatitis A vaccine was part of a clinical trial. No results of such a trial have ever been published or disclosed by the Army. Importantly, there is no indication that the anthrax vaccine used in the clinical trial was the licensed “anthrax vaccine absorbed” (AVA). In its letter to Rep. Shows, the Army would not answer specific questions about the conduct of the clinical trial that were clearly stated.

3. My son was never given informed consent about being an experimental test subject. He developed chronic emotional and physical symptoms following receipt of experimental anthrax-Hepatitis A vaccine. Matthew received two doses in August 1996 and February 1997. After the first dose he developed fever and gastrointestinal cramps, and chronic respiratory congestion. These symptoms became worse after the second dose. He also developed a personality disorder that has continued to this day. My daughter was also an Army soldier, and stationed at Darmstadt, Germany with my son. She was able to monitor the progression of Matthew’s chronic illness following his vaccination. She also reported to us that after the use of experimental vaccines the Darmstadt Army base was placed on a suicide watch. There were two suicides that we know about. One soldier

was also discharged immediately after he was given the vaccine as he was unable to breath.

4. Matthew's subsequent problems are related to brain injury, diagnosed by the Department of Veterans Affairs (VA). After years of evaluation, doctors at the VA hospital in Jackson, Mississippi, finally diagnosed my son with CNS VASCULITIS, SEVERE PERSONALITY DISORDER, OBSTRUCTIVE LUNG DISEASE , AND DEGENERATIVE BONE DISEASE. My son currently lives alone in the mountains of North Carolina.

5. Despite these now-validated, diagnosed medical conditions, my son was given a general discharge prior to the end of his Army enlistment, not a medical discharge. He received no disability rating or psychiatric evaluation. While the Army refused to acknowledge his condition, other government agencies have. Matthew has been granted a 30 percent disability from the Department of Veterans Affairs (which has been under appeal for six years). He is also currently receiving a total disability from the Social Security Administration.

6. I believe my son was the victim of an unethical, and possibly illegal, experiment involving anthrax vaccine. The Department of Defense regularly denies experimenting on servicemembers with anthrax vaccine.³ However, the evidence my son and I developed

³ Assistant Secretary of Defense for Health Affairs, Dr. William Winkenwerder, Dec 23, 2003:

"We -- let me clarify one thing. We do not do experiments on soldiers and service members. We only use licensed FDA products. And if there are, for rarely used types of products, an investigational-type of use, we follow assiduously the guidelines of the FDA in performing those studies."

<http://www.defenselink.mil/transcripts/2003/tr20031223-1062.html>

and presented to Rep. Shows demonstrates that experimentation with anthrax vaccine does occur, and that this may not involve the licensed “anthrax vaccine absorbed” (AVA).

7. The issue currently before the court concerns whether military “volunteers” can take anthrax vaccine without informed consent. First, my son never volunteered to be an experimental test subject for an anthrax vaccine clinical trial, but he was vaccinated anyway. The Army’s refusal to turn over his medical records (see letter to Rep. Shows) demonstrates that they likely knew his records contained no informed consent release signed by my son prior to being vaccinated. Second, there can be no informed consent today unless the cases of servicemembers with chronic illness associated with anthrax vaccine are fully disclosed to recipients. This means that the Army, Merck, and Dr. Jerald Sadoff should be compelled under penalty of perjury to disclose any and all information related to this and any other secret clinical trials involving anthrax vaccine, either AVA or any developmental anthrax vaccine.

8. I have granted permission to those organizations filing a joint amicus brief in opposition to the government’s emergency motion to restart the anthrax vaccine shots to use my son Matthew’s medical records and other documentation. This statement is to certify that the records I have provided these organizations are true and exact copies of his military medical records and related correspondence.

Pursuant to 28 U.S.C. 1746, I declare under penalty that the foregoing is true and correct. Executed this 27th day of February, 2005.

/s/

Steve Turney
122 Robins-Wilkes Rd.
Bassfield, MS 39421

October 10, 1999

Attention; Larry Denman

Congressman Ronnie Shows
245 East Capital. Suite 222
Jackson, Mississippi 39201

Re; Matthew L. Turney

Dear Congressman Shows,

I have a problem with the V.A. and the U.S. Army in getting information I need for my claim.

I went to Darmstadt, Germany in July 1996. In August of 1996 and February 1997 I recieved Hepatitis A vaccine. I need to know the following;

1. The manufacturer of the vaccine.
2. The type of vaccine.
3. The lot numbers of the vaccines I was given.
4. Was Anthrax vaccine given at the same time as the Hepatitis A?
5. Was I in the clinical trials that were sponsored by the D.O.D. of being given Hepatitis A vaccine at the same time as the Anthrax?
6. What safeguards were in place at the time I recieved the Hepatitis A vaccine for adverse reactions?
7. Why didn't they catch the adverse reactions that I experienced?
8. Does the Army usually give the second dose of Hepatitis A vaccine to a person that has an adverse reaction to the first Hepatitis A vaccine, contrary to the drug company warnings?

I also need the name of the Doctor and the medical records where I was sent to the hospital in Mannheim, Germany to see a Psychiatrist in the summer of 1997.

I also need to know why I wasn't given a clinical psychiatric evaluation on October 30, 1997 when I reported for my separation examination.

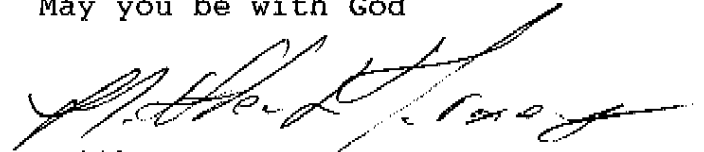
I have enclosed copies of;

1. Merck advertisement.
2. Anthrax on trial with Hepatitis A.
3. My shot record.
4. Medical records after recieving the shots.
5. Copy of Doctor Areno's medical report.

You may talk with my Dad, Steven Turney, about my claim in its' entirety.

I will be looking forward to hearing from you at your earliest convenience.

May you be with God



Matthew L. Turney

Military Medical Technology

Volume 2, Issue 3

GO FOR

U.S. Senator Daniel Inouye

(D-HI) Ranking Democrat
Subcommittee on Defense
Senate Appropriations Committee

*"One of the best kept secrets
of the military is the fact that we have
been spending significant sums of money
developing technology and healthcare
systems and sharing this state-of-the-art
[technology] with the private sector."*

Also in this Issue:

Preparing for Biological Terrorism ★ Stereolithography
LSTAT ★ NBC Emergency Response Team ★ USA/MVA

Industry Interview



Dr. Jerald Sadoff Executive Director Vaccine Infectious Diseases Clinical Vaccine Research Merck & Co., Inc.

One of the "big guns" in virology globally, Jerald Sadoff, M.D., retired from the U.S. Army with the rank of Colonel. Prior to joining Merck & Co. in 1995 where he oversees vaccine infectious diseases, he was Attending Physician on Medicine and Infectious Diseases at the Walter Reed Hospital.

At Merck, Dr. Sadoff is responsible for all vaccine clinical development projects, including *Haemophilus influenza*, *Pneumococcal Polysaccharide*, and *Conjugate*, new pediatric combination vaccines, *Rotavirus*, *Varicella*, *Hepatitis A*, *Hepatitis B*, *Human Papilloma Virus*, *Influenza*, and *HIV*. He has one issued patent and has seven patents pending. Doctor Sadoff also has published more than 120 papers, over 130 abstracts, 27 book chapters, and has edited three books.

Doctor Sadoff currently serves on the Scientific Advisory Board of the International AIDS Vaccine Initiative.

Doctor Sadoff was interviewed by Managing Editor Anthony Kimery.

Q: Talk a little a bit about Merck's approach to vaccine research and development?

A: Merck is investing in high-tech vaccine research at the development stage and in the high-tech manufacturing of vaccines—that's where our strengths are. We are making vaccines in a highly reliable way. Producing vaccines is like finding a needle in a haystack. We are able to take a tiny speck of material—very pure material—and develop our vaccines. This requires advanced technologies, and we think this approach is important.

It takes a lot of work to do it, but my belief is that this high-tech production will increas-

ingly be used to make vaccines that are more reliable, cost-effective, and in larger amounts.

Throughout the industry, more investment will be made when there's a belief, scientifically, that a vaccine will be needed and that it can be developed. We believe that the development of an effective vaccine against HIV is important for human health and are working hard along this path.

These technologies to efficiently produce large critical
ing va
old way

technologies have replaced many old technologies that didn't work as well.

In looking for these high-tech ways to improve vaccines, we also found a new way to insert genes into animal cells, which will allow the bacteria to carry gene-based vaccines to difficult-to-reach parts of the body.

Another challenge is to staying edge of vaccine development receiving an award from the American Society for its work in perfecting manufacturing process that enhances vaccine production as well as the purity of the product. While there's no recognized clinical benefit from a highly purified product that we can identify at this time, the process may lead the way in vaccine production.

We also look at novel ways to approach problems. For example, research is currently ongoing using naked DNA to fight HIV. We use a bacterial plasmid, which is a virus that infects a bacteria. We inject the DNA into muscle and it directs the cells to make whatever gene protein we specify. This includes immune response. This type of modern tool is critically important. Researchers are also looking at modifying viruses so they will express foreign proteins for HIV—these approaches can be applied to all vaccines.

Q: Merck's development of VAQTA, the hepatitis A vaccine, is a good example of Merck's high-tech approach to vaccine research and manufacturing, isn't it?

A: Yes. This vaccine is highly purified and has been developed to the point where in a landmark outcomes trial, VAQTA demonstrat-

ed 100 percent protection against developing hepatitis A illness after a single dose. Throughout development phase, increasingly sophisticated analytical testing has given us a fuller understanding of the viral antigen content of this vaccine. But at the end of the day, what we want are favorable outcomes like that.

Q: Are there any new developments with the Hepatitis A vaccine?

A: Right now we're working with DoD to see whether the Hepatitis A vaccine can be given at the same time as the anthrax vaccine—making it more useful for the military. It would make it easier to give both at the same time than separately in many varied military environments. Clinical trials are sponsored by the DoD.

We try to work with DoD to meet their very specific needs to make our products more useful to the military. The military's needs are different than the civilian populations' and we have to do our work with that in mind.

Q: What else?

A: The use of baker's yeast to make the world's first recombinant vaccine for hepatitis B is yet another example where science creates a product that's better than existing ways of doing things. In creating the vaccine, yeast makes a virus-like particle that to the body looks like hepatitis B virus. The same technology is today being applied to the human Papilloma virus, which causes cervical cancer.

Q: Companies like Merck are best positioned to do vaccine research and development, are they not?

A: Many aspects of vaccine development are best done by the pharmaceutical industry because this is where much of the human experience is; it's where there's personnel, the infrastructure, organization, and it's where there's a flexibility to assign teams of the best people to solve technical problems when they occur. ■



**VAQTA:
Exclusive Contract**

**Because all military
personnel must be
ready to go...**

Protecting the U.S. Military



VAQTA: The only hepatitis A vaccine with demonstrated 100% protection against illness after the first dose in a clinical trial with children and adolescents¹



Merck: The 1997–1998 sole-source provider of adult hepatitis A vaccine available through the Defense Personnel Support Center (DPSC) programs, including:

- Prime Vendor
- SPEDE
- Mail Order Pharmacy
- EDI Phase II
- DVD
- National Mail Order Pharmacy

VAQTA

**(HEPATITIS A VACCINE,
INACTIVATED)**

DEMONSTRATED PROTECTION AGAINST ILLNESS

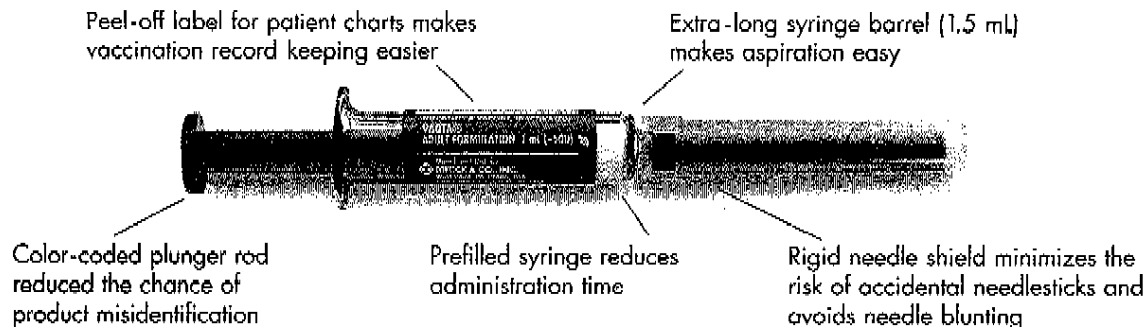
Primary immunization should be given at least 2 weeks prior to expected exposure to hepatitis A virus.

The dosing regimen for VAQTA consists of one primary dose and one booster dose.

As with any vaccine, vaccination with VAQTA may not result in a protective response in all susceptible vaccinees.

Please read the Brief Summary of the full Prescribing Information accompanying this advertisement.

VAQTA: The clear choice for convenience



To order VAQTA, contact your branch logistics command or prime vendor, or to order direct, call 1-800-MERCK-RX (1-800-637-2579)

VAQTA (HEPATITIS A VACCINE, INACTIVATED)

DEMONSTRATED PROTECTION AGAINST ILLNESS

Reference: 1. Wertzberger, A. et al.: A controlled trial of a formalin-inactivated hepatitis A vaccine in healthy children, *N. Engl. J. Med.* 327(7):453-457, August 13, 1992.



Vaccine Division

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982346(1)(500)-VAQ
PRINTED IN U.S.A.

BRIEF SUMMARY

(HEPATITIS A VACCINE, INACTIVATED) VAQTA®

Please read the full Prescribing Information for complete details.

INDICATIONS AND USAGE

VAQTA is recommended in healthy persons 2 years of age and older for active pre-exposure prophylaxis against disease caused by hepatitis A. Primary immunization should be given at least 2 weeks prior to expected exposure to HAV.

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine.

WARNINGS

Individuals who develop symptoms suggestive of hypersensitivity after an injection of VAQTA should not receive further injections of the vaccine (see CONTRAINDICATIONS).

If VAQTA is used in individuals with malignancies or those receiving immunosuppressive therapy or who are otherwise immunocompromised, the expected immune response may not be obtained.

PRECAUTIONS

General

VAQTA will not prevent hepatitis caused by infectious agents other than hepatitis A virus. Because of the long incubation period (approximately 20 to 50 days) for hepatitis A, it is possible for unrecognized hepatitis A infection to be present at the time the vaccine is given. The vaccine may not prevent hepatitis A in such individuals.

As with any vaccine: (1) adequate treatment provisions, including epinephrine, should be available for immediate use should an anaphylactic or anaphylactoid reaction occur; (2) vaccination with VAQTA may not result in a protective response in all susceptible vaccinees.

VAQTA should be administered with caution to people with bleeding disorders who are at risk of hemorrhage following intramuscular injection (see DOSAGE AND ADMINISTRATION).

Any acute infection or febrile illness may be reason for delaying use of VAQTA except when, in the opinion of the physician, withholding the vaccine entails a greater risk.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: VAQTA has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.

Pregnancy Category C: Animal reproduction studies have not been conducted with VAQTA. It is also not known whether VAQTA can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. VAQTA should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether VAQTA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when VAQTA is administered to a woman who is breast feeding.

Pediatric Use: VAQTA has been shown to be generally well tolerated and highly immunogenic in individuals 2 through 17 years of age. Safety and effectiveness in infants below 2 years of age have not been established.

ADVERSE REACTIONS

In combined clinical trials, VAQTA has been generally well tolerated. No serious vaccine-related adverse experiences were observed during clinical trials. As with any vaccine, there is the possibility that use of VAQTA in very large populations might reveal adverse experiences not observed in clinical trials.

In combined clinical trials involving 2595 healthy children and adolescents and 1529 adults, fever and local complaints were observed during a 5-day period following vaccination and systemic complaints during a 14-day period following vaccination. Injection-site complaints, generally mild and transient, were the most frequently reported complaints, and included pain, tenderness, warmth, erythema, swelling, ecchymosis, and pain/soreness. Listed are the complaints (≥1%) reported, without regard to causality: asthenia/fatigue, fever (≥102°F, Oral), abdominal pain, diarrhea, vomiting, nausea, headache, pharyngitis, upper respiratory infection, nasal congestion, cough, myalgia, arm pain, back pain, stiffness, and menstruation disorder. Very few laboratory abnormalities were reported and included isolated reports of elevated liver function tests, eosinophilia, and increased urine protein.

Local and/or systemic allergic reactions that occurred in <1% of children/adolescents or adults in clinical trials regardless of causality included injection site pruritus and/or rash, bronchial restriction, asthma, wheezing, edema/swelling, rash, generalized erythema, urticaria, pruritus, eye irritation/itching, dermatitis (see CONTRAINDICATIONS AND WARNINGS).

DOSAGE AND ADMINISTRATION

Do not inject intravenously, intradermally, or subcutaneously. VAQTA is for intramuscular injection. The deltoid muscle is the preferred site for intramuscular injection.

The vaccination regimen consists of one primary dose and one booster dose for healthy children, adolescents, and adults.

The vaccine should be used as supplied; no reconstitution necessary. Shake well before withdrawal and use. Thorough agitation is necessary to maintain suspension of the vaccine. Discard if the suspension does not appear homogenous. Parenteral drug products should be inspected visually for extraneous particulate matter and discoloration prior to administration whenever solution and container permit. After thorough agitation, VAQTA is a slightly opaque, white suspension. It is important to use a separate sterile syringe and needle for each individual to prevent transmission of infectious agent from one person to another.

MERCK & CO., INC. West Point, PA 19486, USA

ORAL POLIOVIRUS VACCINE

DATE	DOSE	PHYSICIAN'S NAME	DATE	DOSE	PHYSICIAN'S NAME
1 7 MAY 1996	2 gtts.	Constance Kueter MD, CPT, MC	3		
2			4		

INFLUENZA VACCINE

DATE	DOSE	PHYSICIAN'S NAME	DATE	DOSE	PHYSICIAN'S NAME
1 7 MAY 1996	0.5 cc	Constance Kueter MD, CPT, MC	3		
2			4		

OTHER IMMUNIZATIONS

DATE	TYPE	DOSE	PHYSICIAN'S NAME	DATE	TYPE	DOSE	PHYSICIAN'S NAME
1 7 MAY 1996	MGC	0.5cc	Constance Kueter, MD, CPT	5 Feb 97	HepA#2	.5cc	Arboursky
2 7 MAY 1996	MR	0.5cc	Constance Kueter, MD, CPT	6			
3 7 MAY 1996	Adenovirus	4&7	Constance Kueter, MD, CPT	7			
4 Aug 96	HepA#1	.5cc	Angela Brown	8			

SENSITIVITY TESTS (Tuberculin, etc.)

DATE	TYPE	DOSE	ROUTE	RESULTS	PHYSICIAN'S NAME
1 7 MAY 1996	PPD	0.1cc	LFA	0.1cc	Constance Kueter, MD, CPT
2					
3					
4					
5					

REMARKS:

This is to certify that the soldier received seven immunizations.

7 MAY 1996

DST PRIMARY CARE

TIROL, TRISTAN G

13 Sep 1996

0900

NEW

BHAR

REF:

CMT: ERC

RSN:

BP: ¹⁰⁰/₆₀ PULSE: 72 RESP: 16 TEMP: 99.8 HT: 64 1/2 WT: 125 lbs

=====

ADDITIONAL COMMENTS:

S 214/10 of C/O fever, stomach cramps, diarrhea
x 3 Days. SPC R. Cal 910N

T: 1/13

BP 95/58

P 72

P BP 104/62

P 76

S. bones of lower

- inner. 1 PPD

Coughing x 3 days

- neck: 0

Lower B.M. 5x/day

- allg. NKHA

no vom. Hx

nausea: large production

? mucus Hx; 7/10/96 but inj.

O. clear, ambulatory 10x

Heart: Tn & Throat clear

- inner: negative

- hyp. clear 6x

- abdomen: flat, soft, 10x 2x

A) Aorta 6E

- Tylenol - 325 mg - 2g 4x

(1) 24 in 0x

- Acetaminophen - 1 PPD

- Bactrim DS - 7 1/2 x 10 x 100 10x

20/587-57-3863

TURNER, MATTHEW

A11

25 May 1975 MALE

W:

H: 6017368285

Spon: TURNER, MATTHEW

CIC:

CS:

Rank: PFC

D:

SF600

Unit: 0596 CS CO

MAINT

RR: DST RECORD ROOM

Shin #6

PRIMARY CARE

BRAGA, ESPERANZA B

19 Mar 1997

0930

SCAD

BHAK

ONE LUNG

Allergies - NKOA

Med's - Proventil, Theophylline

127/70

80

RES

20

TEMP

97.8

64"

150 lbs

S- 21 y.o. F here for F/U on fluid in lung causing breathing problems.

Det Jose D. On 9/1/82

very personal.

Recurrent Bronchitis since Feb 94 by history.

Smoke 1 pack/day (1 pack/day) Smokes for almost 3 years.

(2) HESIT. - Asymptomatic slightly enlarged. 7 related

Lungs - clear to AP.

Heart - normal.

Abdomen - unremarkable.

4/ cough.

1/2 chest X-ray in AP.

CBC - fully

repeated. addition to SFG Smokes/Respirator

R + L in AP for chest X-ray

AP of lateral.

Signature: [Signature]

USAHC DARMSTADT

098 - 58 - 6369

BRAGA ESPERANZA

MD MAJ MC

Epithelial # 8

CLINIC
CONTINUATION RECORD

02/04/1999 Turney, Matthew
John Paul Arena, M.D.

260385-0

REFERRED BY: Self-referral.

CHIEF COMPLAINT: Respiratory problems.

HISTORY OF PRESENT ILLNESS: Patient is 23 year old white male who states that his initial problems began back in August 1996. He had been in the Army at that time and had been doing fairly well with no significant respiratory problems. His father and he relate it to an hepatitis A vaccine which he received. Sometime afterward he developed some fever, abdominal cramps and other problems that they felt may be secondary to his vaccination. Shortly afterwards he began to develop recurrent respiratory tract infections and was diagnosed with mild asthma while he was in the service. His symptoms continued to progress with increased productive of phlegm and dyspnea on exertion to the point where he was unable to perform necessary exercises and task. In looking through his records he had been treated with Proventil and Azmacort inhalers as well as a variety of antibiotics. He eventually was discharged and since then he has had some mental problems including development of bipolar disorder as well as substance abuses. He and his father are here today for a pulmonary evaluation and to see if there is anything specific with regards to treatment. In speaking with him regarding his pulmonary symptoms he seems to have occasional cough which is productive of some clear to yellowish phlegm and predominantly dyspnea on exertion. He denies any pleuritic type chest pain. He has not had any PND or orthopnea. No recent fever or chills have been noted. He does note that his dyspnea seems to be worse with exertion. He denies any pain which is associated with this. He has not noted any weight loss over the previous duration, either.

PAST MEDICAL HISTORY: Really unremarkable except as mentioned above.

PAST SURGICAL HISTORY: Negative.

MEDICATIONS: Depakote which he takes for his bipolar disorder.

ALLERGIES: None known.

HABITS: He does have a history of smoking and is currently smoking about 1/2 pack a day of cigarettes. Has had some occasional ethanol use but denies any recent use. He does have a history of drug use as well.

CONFIDENTIAL FURTHER DISCLOSURE
IS PROHIBITED.

Exhibit # 11-C

CONTINUED - PAGE 2

OCCUPATIONAL HISTORY: Has been in the Army. Has not had any recent jobs since then except for some odd ones here and there. He did have a period of time where he was welding and was exposed to a little bit of smoke exposure but has no known toxic exposures.

FAMILY HISTORY: His father has some mild emphysema from smoking, otherwise unremarkable.

REVIEW OF SYSTEMS:

General: Some occasional fatigue, particularly with exertion. No recent fevers, chills, or weight loss.

HEENT: Negative for earache, sore throat, or headache.

Pulmonary: As above.

CV: Negative for any anginal type chest pains or palpitations.

GI: Negative.

GU: Negative.

Neuro: Negative.

Psych: Significant for his history of bipolar disorder and substance abuse.

Hem/Onc: Negative.

Endo: Negative.

MS: Negative.

PHYSICAL EXAMINATION:

V.S.: Afebrile. P - 80 BP - 110/60

General: Well-developed, white male in no acute distress.

HEENT: Oropharynx is clear. Nasopharynx without lesions.

Neck: Supple, full range of motion. No JVD or thyromegaly noted.

Heart: Regular rate and rhythm with no murmurs, gallops, or rubs.

Lungs: Show a very light, occasional end expiratory wheeze particularly in the middle to upper lung fields. Respiratory effort is non-labored. There is no dullness to percussion or tactile fremitus.

Abdomen: Soft, nontender, nondistended, without masses. No hepatosplenomegaly.

Extremities: No clubbing, cyanosis, or edema. Nail beds have good capillary refill.

Skin: Warm and dry with good turgor. No abnormal rashes noted.

Lymphatics: Reveals no palpable supraclavicular or submandibular lymphadenopathy.

Neurologic: Cranial nerves were intact. There were no focal motor or sensory deficits elicited.

Psychiatric: Mood and affect appear to be a little bit flat. He is alert and oriented and responds to questions appropriately.

Chest x-ray: Shows no acute infiltrates, effusions, or other abnormalities save for a few calcified granulomas.

Spirometry: Revealed an FEV1 of 2.74 which is 70% of predicted, FVC 3.47 which is 76% of predicted, and a ratio of 79%. FEF-2575 is reduced at 58% of predicted. These findings are consistent with early obstructive ventilatory impairment. O2 sat on room air is 98%.

CONFIDENTIAL
OTHER DISCLOSURE
IS PROHIBITED.

IMPRESSION:

CONTINUED - PAGE 3

1. Asthma, probably of a mild persistent nature.
2. Possible reaction to a previous hepatitis vaccine.

PLAN: I discussed etiology and treatments and other aspects of asthma with patient and his father. Right now I am going to start him on Proventil HFA at 2 puffs q.i.d. which we will continue for a month as well as Flovent 110, 2 puffs b.i.d. When he returns back we may be able to hopefully wean him down and just p.r.n. Proventil. He has been given MDI instructions. I have asked him to notify us should he have any change in his signs or any worsening of his respiratory symptoms.

John Paul Areno, M.D.
/kjr

THIS INFORMATION IS PRIVILEGED AND
CONFIDENTIAL FURTHER DISCLOSURE
IS PROHIBITED.



UNITED STATES ARMY

Dear Dad,

Well dad how is it going, hopefully
your catching all the fish. Catch a muskie
for me alright. Well Dad I'm almost out
of here, not very much longer till I'm cooking
it in Wisconsin. I'm ready for some good
old quiet fishing. We are now done with
Basic Rifle Marksmanship I qualified
Marksman, I wanted Hawkeye BUT ok
well sorry about that. That is what my
female Drill Sgt. always says. I
also fired a grenade launcher, the AT-4
of missile launcher and 50 rounds out of
the M60, the M60 disappointed me I
thought that it would have had more power
but it was alright I guess. We are now
at Blue Phase, we have FTX we went
for 3 days 2 nights of bivouac. We got
to crawl under barbed wire while they shoot over
us. That will be cool. I can't wait to see the
girls's expressions. Then we have graduation
practice and then we graduate. Not a whole
lot left. I has ~~been~~ been a real ~~good~~
experience and a lot of fun BUT I will
be ready to hit my permanent duty station.
oh yeah, they were offering me Airborne
the other day BUT the said that I could not
go to Germany any time soon and no telling
whether or not I would have better my
extra rank after Basic so I turned them
down. the Drill Sgt. is messed with me a
S.I.D. - 0 - 4

Little bit But that was not it. He knows
that I am Really Ready to Hit Germany with a
Bang. I smoked my P. +. Test Today. I got
78 PUGL UPS, 68 SITUPS and Ran 15 min 29 sec.
on my 2 mile Run. I was the second Highest.
next P + test and Last P. +. Test is Friday
and I am going to smoke everyone, well dad
I love ya and cant wait to wake up Real early
with ya and do some fishing But till then I
Love ya and tell every one else that I Love
them & Goodnight.

P.S. Latel me the Bibbest
Muskie

Your son
Mickie



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
OFFICE OF THE CHIEF OF LEGISLATIVE LIAISON
1600 ARMY PENTAGON
WASHINGTON DC 20310-1600

November 8, 1999

The Honorable Ronnie Shows
Representative in Congress
245 East Capitol, Suite 222
Jackson, Mississippi 39201

Dear Congressman Shows:

This replies to your inquiry on behalf of Mr. Matthew L. Turney, concerning his medical care while in the Army.

Army officials in Germany advise that the U. S. Army Hospital, Heidelberg (USAH-H), Germany, reports that the Commander, U. S. Army Health Clinic, Darmstadt (USAHC-D), the Officer-in-Charge (OIC), Immunization Clinic, and the Chief, Psychiatry, USAH-H, all reviewed Mr. Turney's case.

The Clinic Commander's review revealed that the USAHC-D followed and continues to follow the safeguards for adverse reactions to Hepatitis and other vaccines, as outlined in Army Regulation (AR) 40-501. Specifically, patients are queried as to whether they have had a history of hypersensitivity or allergy to an immunizing agent, in which case they would ordinarily be medically exempt from that immunization. Persons with questionable history of adverse reaction should undergo an allergy evaluation to determine if hypersensitivity exists. Patients are instructed to wait 20 minutes before leaving the clinic after receiving a shot. Adverse reactions are described in detail in the individuals medical record, along with specific identification of the biologic agent, the lot number and manufacturer, and the date, name, and location of the medical facility. This is documented in the patients' medical record and is now documented in the Army's Composite Health Care System (CHCS); however, this information is not available to Mr. Turney, because his medical record has been retired and the immunization module was not placed on CHCS until late 1997. Mr. Turney can request a copy of his former military health records from the National Personnel Records Center (NPRC) in St. Louis, Missouri, where his medical records were sent upon his separation from the military. To be of assistance, I have forwarded Mr. Turney's inquiry to the NPRC for appropriate action with this matter.

The Monroe Efficacy Study, provided by Merk, reported that out of 1037 children and adolescents who received both the Hepatitis A vaccine and booster, 2.7 percent reported pharyngitis, 2.8 upper respiratory infection, and 1.1 percent nasal congestion. This compared with 0.8 percent of patients who received placebo, which is not significantly different.

The Chief, Preventive Medicine, Europe Regional Medical Command, is not aware of any such reaction in taking both the Anthrax and Hepatitis A vaccines together and felt this was safe. A brief search on the Anthrax website did not provide any information regarding this question.

The Officer-In-Charge (OIC) Immunization Clinic, USAH-H, states that all Immunization Clinics in their catchment area adhere to Medical Command (MEDCOM) guidelines relating to the diagnosis and treatment of immediate adverse reactions caused by vaccines. Immunization staff are trained to react to immediate systemic and local reactions from immunizations, to include anaphylaxis and local skin reactions. From reviewing Mr. Turney's limited medical records available, it appears that Mr. Turney's supposed reaction took the form of latent side effects that would not have been observed in the Immunization Clinic, due to the timeframe in which they took place.

Immunization Clinic staff would never give a second dose of any immunization if a reaction was noted in the first immunization. If Mr. Turney had a reaction after he left the Immunization Clinic, he would have been responsible for notifying the Immunization Clinic staff prior to receiving the second immunization. The information available indicates there are no new developments regarding either forms of the Hepatitis A vaccine.

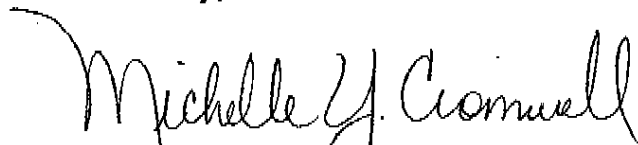
According to the manufacturer's information for the vaccines, the Physician's Desk Reference found possible side effects caused by the vaccines similar to those experienced by Mr. Turney include: fever --101 degrees, abdominal pain, upper respiratory tract infection, pharyngitis, and nasal congestion. According to the manufacturer, these side effects are usually experienced during the 14 days directly after injection and do not vary significantly from the placebo. The vast majority of immunization side effects present themselves as local reactions (pain at injection site, swelling, redness, etc.) up to 72 hours after injection. The available medical records do not indicate that Mr. Turney returned to the clinic during this period to complain of discomfort. Immunizations, such as Hepatitis A, typically do not cause lingering health problems, such as asthma and recurrent upper respiratory tract infections; rather, these complaints of Mr. Turney are probably more closely related to his smoking habit, as outlined in the pulmonology consultation by Dr. Aren0, dated February 4, 1999.

The Department of Psychiatry, USAH-H, reported Mr. Turney was seen by one of their psychiatrists. The Patient Administration Division (PAD), USAH-H, is mailing a copy of Mr. Turney's psychiatric record directly to him.

Under the provisions of AR 635-200, paragraph 1-34, and depending on the type of chapter action, a soldier separating from active duty does require a mental health evaluation. The personnel at the examination station would not know to accomplish the evaluation unless they knew the type of chapter. The Department of Psychiatry did not receive a request or consult to do such an exam; therefore, none was done for Mr. Turney.

Thank you for your interest in this matter. I trust this information will be of assistance.

Sincerely,



Michelle Y. Cromwell
Congressional Coordinator
Congressional Inquiry Division

Military Medical Technology

Volume 2, Issue 3

GO FOR

U.S. Senator Daniel Inouye

**(D-HI) Ranking Democrat
Subcommittee on Defense
Senate Appropriations Committee**

*"One of the best kept secrets
of the military is the fact that we have
been spending significant sums of money
developing technology and healthcare
systems and sharing this state-of-the-art
[technology] with the private sector."*

Also in this Issue:

**Preparing for Biological Terrorism ★ Stereolithography
LSTAT ★ NBC Emergency Response Team ★ USAIMIA**

VAQTA:
Exclusive Contract

**Because all military
personnel must be
ready to go...**

Protecting the U.S. Military



VAQTA: The only hepatitis A vaccine with demonstrated 100% protection against illness after the first dose in a clinical trial with children and adolescents¹



Merck: The 1997-1998 sole-source provider of adult hepatitis A vaccine available through the Defense Personnel Support Center (DPSC) programs, including:

- Prime Vendor
- SPEDE
- Mail Order Pharmacy
- EDI Phase II
- DVD
- National Mail Order Pharmacy

VAQTA

**(HEPATITIS A VACCINE,
INACTIVATED)**

DEMONSTRATED PROTECTION AGAINST ILLNESS

Primary immunization should be given at least 2 weeks prior to expected exposure to hepatitis A virus.

The dosing regimen for VAQTA consists of one primary dose and one booster dose.

As with any vaccine, vaccination with VAQTA may not result in a protective response in all susceptible vaccinees.

Please read the Brief Summary of the full Prescribing Information accompanying this advertisement.

VAQTA: The clear choice for convenience

Peel-off label for patient charts makes vaccination record keeping easier

Extra-long syringe barrel (1.5 ml) makes aspiration easy



Color-coded plunger rod reduced the chance of product misidentification

Prefilled syringe reduces administration time

Rigid needle shield minimizes the risk of accidental needlesticks and avoids needle blunting

To order VAQTA, contact your branch logistics command or prime vendor, or to order direct, call 1-800-MERCK-RX (1-800-637-2579)

VAQTA (HEPATITIS A VACCINE, INACTIVATED)

DEMONSTRATED PROTECTION AGAINST ILLNESS

Reference: 1. Wertzberger, A. et al.: A controlled trial of a formalin-inactivated hepatitis A vaccine in healthy children, *N. Engl. J. Med.* 327(7):453-457, August 13, 1992.



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982346 (1)(500)-VAQ
PRINTED IN U.S.A.

BRIEF SUMMARY

(HEPATITIS A VACCINE, INACTIVATED) VAQTA®

Please read the full Prescribing Information for complete details.

INDICATIONS AND USAGE

VAQTA is recommended in healthy persons 2 years of age and older for active pre-exposure prophylaxis against disease caused by hepatitis A. Primary immunization should be given at least 2 weeks prior to expected exposure to HAV.

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine.

WARNINGS

Individuals who develop symptoms suggestive of hypersensitivity after an injection of VAQTA should not receive further injections of the vaccine (see CONTRAINDICATIONS).

If VAQTA is used in individuals with malignancies or those receiving immunosuppressive therapy or who are otherwise immunocompromised, the expected immune response may not be obtained.

PRECAUTIONS

General

VAQTA will not prevent hepatitis caused by infectious agents other than hepatitis A virus. Because of the long incubation period (approximately 20 to 50 days) for hepatitis A, it is possible for unrecognized hepatitis A infection to be present at the time the vaccine is given. The vaccine may not prevent hepatitis A in such individuals.

As with any vaccine: (1) adequate treatment provisions, including epinephrine, should be available for immediate use should an anaphylactic or anaphylactoid reaction occur; (2) vaccination with VAQTA may not result in a protective response in all susceptible vaccinees.

VAQTA should be administered with caution to people with bleeding disorders who are at risk of hemorrhage following intramuscular injection (see DOSAGE AND ADMINISTRATION).

Any acute infection or febrile illness may be reason for delaying use of VAQTA except when, in the opinion of the physician, withholding the vaccine entails a greater risk.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: VAQTA has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.

Pregnancy Category C: Animal reproduction studies have not been conducted with VAQTA. It is also not known whether VAQTA can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. VAQTA should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether VAQTA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when VAQTA is administered to a woman who is breast feeding.

Pediatric Use: VAQTA has been shown to be generally well tolerated and highly immunogenic in individuals 2 through 17 years of age. Safety and effectiveness in infants below 2 years of age have not been established.

ADVERSE REACTIONS

In combined clinical trials, VAQTA has been generally well tolerated. No serious vaccine-related adverse experiences were observed during clinical trials. As with any vaccine, there is the possibility that use of VAQTA in very large populations might reveal adverse experiences not observed in clinical trials.

In combined clinical trials involving 2595 healthy children and adolescents and 1529 adults, fever and local complaints were observed during a 5-day period following vaccination and systemic complaints during a 14-day period following vaccination. Injection-site complaints, generally mild and transient, were the most frequently reported complaints, and included pain, tenderness, warmth, erythema, swelling, ecchymosis, and pain/soreness. Listed are the complaints (≥1%) reported, without regard to causality: asthenia/fatigue, fever (≥102°F, Oral), abdominal pain, diarrhea, vomiting, nausea, headache, pharyngitis, upper respiratory infection, nasal congestion, cough, myalgia, arm pain, back pain, stiffness, and menstruation disorder. Very few laboratory abnormalities were reported and included isolated reports of elevated liver function tests, eosinophilia, and increased urine protein.

Local and/or systemic allergic reactions that occurred in <1% of children/adolescents or adults in clinical trials regardless of causality included injection site pruritus and/or rash, bronchial restriction, asthma, wheezing, edema/swelling, rash, generalized erythema, urticaria, pruritus, eye irritation/itching, dermatitis (see CONTRAINDICATIONS and WARNINGS).

DOSAGE AND ADMINISTRATION

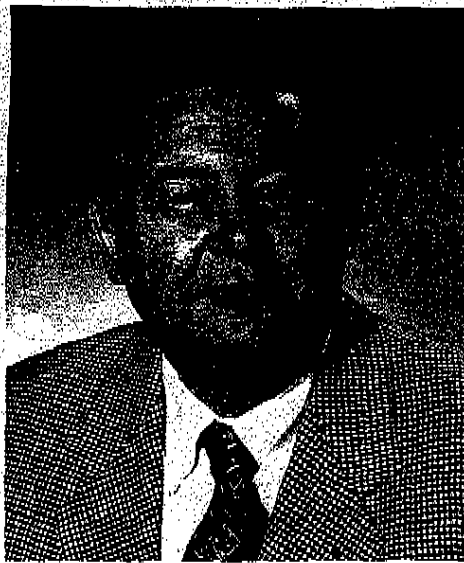
Do not inject intravenously, intradermally, or subcutaneously. VAQTA is for intramuscular injection. The deltoid muscle is the preferred site for intramuscular injection.

The vaccination regimen consists of one primary dose and one booster dose for healthy children, adolescents, and adults.

The vaccine should be used as supplied; no reconstitution necessary. Shake well before withdrawal and use. Thorough agitation is necessary to maintain suspension of the vaccine. Discard if the suspension does not appear homogeneous. Parenteral drug products should be inspected visually for extraneous particulate matter and discoloration prior to administration whenever solution and container permit. After thorough agitation, VAQTA is a slightly opaque, white suspension. It is important to use a separate sterile syringe and needle for each individual to prevent transmission of infectious agent from one person to another.

MERCK & CO., INC. West Point, PA 19486, USA

Industry Interview



Dr. Jerald Sadoff Executive Director Vaccine Infectious Diseases Clinical Vaccine Research Merck & Co., Inc.

One of the "big guns" in virology globally, Jerald Sadoff, M.D., retired from the U.S. Army with the rank of Colonel. Prior to joining Merck & Co. in 1995 where he oversees vaccine infectious diseases, he was Attending Physician on Medicine and Infectious Diseases at the Walter Reed Hospital.

At Merck, Dr. Sadoff is responsible for all vaccine clinical development projects, including *Haemophilus influenza*, *Pneumococcal Polysaccharide*, and *Conjugate*, new pediatric combination vaccines, *Rotavirus*, *Varicella*, *Hepatitis A*, *Hepatitis B*, *Human Papilloma Virus*, *Influenza*, and *HIV*. He has one issued patent and has seven patents pending. Doctor Sadoff also has published more than 120 papers, over 130 abstracts, 27 book chapters, and has edited three books.

Doctor Sadoff currently serves on the Scientific Advisory Board of the International AIDS Vaccine Initiative.

Doctor Sadoff was interviewed by Managing Editor Anthony Kimery.

Q: Talk a little a bit about Merck's approach to vaccine research and development?

A: Merck is investing in high-tech vaccine research at the development stage and in the high-tech manufacturing of vaccines—that's where our strengths are. We are making vaccines in a highly reliable way. Producing vaccines is like finding a needle in a haystack. We are able to take a tiny speck of material—very pure material—and develop our vaccines. This requires advanced technologies, and we think this approach is important.

It takes a lot of work to do it, but my belief is that this high-tech production will increas-

ingly be used to make vaccines that are more reliable, cost-effective, and in larger amounts.

Throughout the industry, more investment will be made when there's a belief, scientifically, that a vaccine will be needed and that it can be developed. We believe that the development of an effective vaccine against HIV is important for human health and are working hard along this path.

These technologies to efficiently produce large quantities of vaccines are very vital and critical technologies—Our approach to making vaccines can hardly be compared to the old ways things were done years ago. High technologies have replaced many old technologies that didn't work as well.

In looking for these high-tech ways to improve vaccines, we also found a new way to insert genes into animal cells, which will allow the bacteria to carry gene-based vaccines to difficult-to-reach parts of the body.

Another challenge is to stay on the leading edge of vaccine development. Merck is receiving an award from the American Chemical Society for its work in perfecting a new manufacturing process that enhances vaccine production as well as the purity of the product. While there's no recognized clinical benefit from a highly purified product that we can identify at this time, the process may lead the way in vaccine production.

We also look at novel ways to approach problems. For example, research is currently ongoing using naked DNA to fight HIV. We use a bacterial plasmid, which is a virus that infects a bacteria. We inject the DNA into muscle and it directs the cells to make whatever gene protein we specify. This includes immune response. This type of modern tool is critically important. Researchers are also looking at modifying viruses so they will express foreign proteins for HIV—these approaches can be applied to all vaccines.

Q: Merck's development of VAQTA, the hepatitis A vaccine, is a good example of Merck's high-tech approach to vaccine research and manufacturing, isn't it?

A: Yes. This vaccine is highly purified and has been developed to the point where in a landmark outcomes trial, VAQTA demonstrat-

ed 100 percent protection against developing hepatitis A illness after a single dose. Throughout development phase, increasingly sophisticated analytical testing has given us a fuller understanding of the viral antigen content of this vaccine. But at the end of the day, what we want want are favorable outcomes like that.

Q: Are there any new developments with the Hepatitis A vaccine?

A: Right now we're working with DoD to see whether the Hepatitis A vaccine can be given at the same time as the anthrax vaccine—making it more useful for the military. It would make it easier to give both at the same time than separately in many varied military environments. Clinical trials are sponsored by the DoD.

We try to work with DoD to meet their very specific needs to make our products more useful to the military. The military's needs are different than the civilian populations' and we have to do our work with that in mind.

Q: What else?

A: The use of baker's yeast to make the world's first recombinant vaccine for hepatitis B is yet another example where science creates a product that's better than existing ways of doing things. In creating the vaccine, yeast makes a virus-like particle that to the body looks like hepatitis B virus. The same technology is today being applied to the human Papilloma virus, which causes cervical cancer.

Q: Companies like Merck are best positioned to do vaccine research and development, are they not?

A: Many aspects of vaccine development are best done by the pharmaceutical industry because this is where much of the human experience is; it's where there's personnel, the infrastructure, organization, and it's where there's a flexibility to assign teams of the best people to solve technical problems when they occur. ■

ORAL POLIOVIRUS VACCINE

DATE	DOSE	PHYSICIAN'S NAME	DATE	DOSE	PHYSICIAN'S NAME
1 7 MAY 1996	2 gtts.	Constance Kueter MD, CPT, MC	3		
2			4		

INFLUENZA VACCINE

DATE	DOSE	PHYSICIAN'S NAME	DATE	DOSE	PHYSICIAN'S NAME
1 7 MAY 1996	0.5 cc	Constance Kueter MD, CPT, MC	3		
2			4		

OTHER IMMUNIZATIONS

DATE	TYPE	DOSE	PHYSICIAN'S NAME	DATE	TYPE	DOSE	PHYSICIAN'S NAME
1 7 MAY 1996	MGC	0.5cc	Constance Kueter, MD, CPT	5 12-97	HepA#2	.5cc	Angela Horvath
2 7 MAY 1996	MR	0.5cc	Constance Kueter, MD, CPT	6			
3 7 MAY 1996	Adenovirus	4&7	Constance Kueter, MD, CPT	7			
4 Aug 96	HepA#1	.5cc	Angela Horvath	8			

SENSITIVITY TESTS (Tuberculin, etc.)

DATE	TYPE	DOSE	ROUTE	RESULTS	PHYSICIAN'S NAME
1 7 MAY 1996	PPD	0.1cc	LEA	0.1MM	Constance Kueter, MD, CPT
2					
3					
4					
5					

REMARKS:

This is to certify that the soldier received seven immunizations.

7 MAY 1996

DST PRIMARY CARE

TIROL, TRISTAN G

13 Sep 1996

0900

NEW

BHA

REF:

CMT: ERC

RSN:

BP: 100/60 PULSE: 72 RESP: 16 TEMP: 99.8 HT: 64in WT: 125lbs

ADDITIONAL COMMENTS:

S 214/10 of C/O fever, stomach cramps, diarrhea
x 3 Days. SPC R. Calm 9/15/96

7/1/75
BP 95/58 P 72
Q BP 104/62 P 76

S. bone of arm

- Jumper. 1 PPD

Congestive x 3 days

- med: 8

long BM 5x/day

- allergy: N/A

no vom. Hx

nausea: large production

? possible Hx: 7 days low inj.
O. clear, ambulatory 10x

- heart: Dr & Thrombosis

- med: none

- hyp. clear 6x

- abdomen: flat, soft, no Hx

A) Acute 6E

- Tylenol - 325mg - 2g 4x

(1) 24 in 8x

- Acetaminophen - 1000mg

- Bactrim DS - 7 Hx. S.P. x 10x

Dx

20/587-57-3863

TURNER, MATTHEW

A11

- PTC as necessary
H: 6017368285

25 May 1975 MALE

W:

Spon: TURNER, MATTHEW

CIC:

CS:

Rank: PFC

D:

Unit: 0596 CS CO

MAINT

RR: DST RECORD ROOM

S. Hx #6

PRIMARY CARE

BRAGA, ESPERANZA S

19 Mar 1997

0830

SCAD

2HAK

ENT LUNGE

Allergies - NKDA Meds - Proventil, Procydine

127/70

80

DEC

20

TEMP

97.5

64"

150 lbs

S-21 y.o. ♂ here for F/U on fluid in lung causing running problems.

they returned. Sgt Jose D. On 9/18/20

Recurrent Bronchitis since Feb 96 by history.

Proventil inhaler (1 puff/day) Smokes for almost 3 years. @ occasional / day. Cough. No difficulty breathing. (2) HEENT - Oropharynx slightly erythematous. 9/18/20

Lungs - clear to AP.

Heart - normal.

Abdomen - unremarkable.

H/1 Cough.

1/2 chest x-ray in AP.

CBC - normal. egapacol. active & stable smoking / heavy.

Rt + Lt in AP for chest x-ray

AP & lateral.

Sgt Jose D. On 9/18/20

USAMC DARMSTADT
098 - 58 - 6969
BRAGA ESPERANZA
MD MAJ MC